

**ENTERED**

March 29, 2022

Nathan Ochsner, Clerk

UNITED STATES DISTRICT COURT  
SOUTHERN DISTRICT OF TEXAS  
HOUSTON DIVISION

DEBORAH BARONE,

Plaintiff,

VS.

ETHICON INC, *et al.*,

Defendants.

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CIVIL ACTION NO. 4:20-CV-03950

**ORDER**

Before the Court are three motions: first, Defendants’ Motion to Limit the Case-Specific Opinions of Dr. Paul J. Michaels (“Motion to Limit Dr. Michaels,” Doc. #140), Plaintiff’s Response (Doc. #150), and Defendants’ Reply (Doc. #152); second, Defendants’ Motion to Exclude Certain Case-Specific Opinions of Daniel S. Elliott, M.D. (“Motion to Limit Dr. Elliott,” Doc. #141), Plaintiff’s Response (Doc. #149), and Defendants’ Reply (Doc. #153); and third, Defendants’ Motion to Bifurcate Trial (“Motion to Bifurcate,” Doc. #155), Plaintiff’s Response (Doc. #156) and Defendants’ Reply (Doc. #157). Having considered the parties’ arguments and applicable law, the Court denies all three Motions.

**I. Background**

**a. Factual Background**

On March 27, 2007, Ms. Deborah Barone (“Barone” or “Plaintiff”) elected to undergo surgery at Memorial City Hospital in Houston, Texas, to treat her stress urinary incontinence and pelvic organ prolapse. Doc. #140, Ex. 1 at 63, 65, 71–73. During this surgery, Melvyn A. Anhalt, M.D. (“Dr. Anhalt”) implanted a Total Prolift Total Anterior and Posterior transvaginal mesh device to treat Barone’s pelvic organ prolapse and a tension-free vaginal tape-obturator (“TVT-

O”) to treat her stress urinary incontinence. *Id.* During the same surgery, Dr. P. Frank Ronen (“Dr. Ronen”) performed a total vaginal hysterectomy and removed an ovary and a fallopian tube. *Id.* at 91.

Following her pelvic repair surgery, Barone continued to complain of pelvic pain and she underwent several revision surgeries. On August 6, 2007, Dr. Anhalt performed a revision and excision of some of the mesh. Doc. #150, Ex. 1 at 3. On March 3, 2008, Christina K. Pramudji, M.D., (“Dr. Pramudji”) performed a second Prolift mesh revision. Doc. 140, Ex. 1 at 99; Doc. #150, Ex. 5. On August 14, 2012, Dr. Pramudji conducted yet another revision surgery, performing an anterior and posterior excision of mesh from the Prolift device. Doc. #140, Ex. 1 at 104–05; Doc. #150, Ex. 6. In April of 2014, Barone saw Dr. Peter Lotze (“Dr. Lotze”), complaining of vaginal pain. On examination, Dr. Lotze recommended another mesh revision surgery, which he performed on August 13, 2014. Doc. #140, Ex. 1, at 117, 134; Doc. #150, Ex. 7. On July 20, 2015, Dr. Lotze performed another surgery to attempt another excision of mesh from the posterior Prolift. However, during the surgery, he determined that he could not do so safely. Doc. #140, Ex. 1 at 121, 128; Doc. #150, Ex. H. On September 11, 2018, Barone underwent total removal of her TVT-O by Dr. Michael Hibner (“Dr. Hibner”). Doc. #150, Ex. 9.

Dr. Paul J. Michaels (“Dr. Michaels”) and Daniel S. Elliot (“Dr. Elliot”) are Plaintiff’s designated expert witnesses. Doc #141 Ex. 6. Dr. Michaels received his medical degree from the University of California, Los Angeles School of Medicine and is board-certified in anatomic pathology, clinical pathology, and cytopathology. Doc. #150, Ex. 1 at 1. Dr. Michaels has testified that, in forming his case-specific opinions, he re-reviewed numerous textbooks, online pathology sources, medical literature, internal Ethicon documents, and depositions and expert reports from other physicians. Doc. #150, Ex. 16, at 4, 5. Dr. Michaels also testified about how he develops his case specific diagnoses by utilizing clinico-pathological correlation and a differential

diagnosis. *Id.* at 6–13. Dr. Elliott is an associate professor of urology in the section of Female Urology and Reconstructive Surgery at the famed Mayo Clinic Graduate School of Medicine in Rochester, Minnesota and specializes in treating urinary incontinence in women. Doc. #149, Ex. 2 at 1, 2. Dr. Elliot purports to have based his opinions in this case on his personal examination of Plaintiff, a thorough review of her medical records, his extensive experience and training, and his review of a large amount of relevant medical literature and corporate documents. *Id.* at 2–4, 57–67.

**b. Procedural Background**

On October 19, 2012, Plaintiff filed a short form complaint in the U.S. District Court for the Southern District of West Virginia in the *In re: Ethicon, Inc. Pelvic Repair System Products Liability Litigation*, No. 2:21-MD-2327 (“MDL”), which incorporated by reference the First Amended Master Long Form Complaint. *See* Doc. #1 and Doc. #103, Ex. 1. While pending in the MDL for pretrial proceedings before the Honorable Joseph R. Goodwin, the parties conducted discovery and exchanged disclosures of their respective general and case-specific expert witnesses and reports, including the reports of Dr. Michaels and Dr. Elliot. Dr. Michaels disclosed his initial report on May 22, 2017. Doc. 150, Ex. 1. Dr. Elliot disclosed his initial report on May 18, 2018. Doc. #149, Ex. 1. On August 14, 2017, pursuant to the MDL Court’s deadline of August 15, 2017, Defendants filed their initial Motions to Exclude the Case-Specific Opinions of Dr. Michaels and to Exclude the Case-Specific Opinions of Dr. Elliot. Doc. #60; Doc. #61; Doc. #62; and Doc. #63.

On August 19, 2019, Dr. Michaels amended his report, based upon new evidence and treatment that took place between his two reports. Doc. #150, Ex. 2. On September 9, 2019, Dr. Elliott did the same. Doc. #149, Ex. 2. Although having previously ruled on both doctors’ general causation opinions, the MDL Court did not rule on their case-specific opinions prior to the transfer to Judge Charles Eskridge in the Southern District of Texas. On March 4, 2021, after Judge

Eskridge held his Initial Conference, the Court permitted Defendants to re-file their case-specific *Daubert* briefs to incorporate Fifth Circuit law. *See* Minute Entry, March 4, 2021. Thereafter, Defendants filed their Motion to Limit Dr. Michaels and Motion to Limit Dr. Elliott on April 9, 2021. Doc. #140 and Doc. #141. Defendants filed their Motion to Bifurcate on August 20, 2021. Doc. #155. A motion hearing was set for all three motions on January 4, 2022, but Judge Eskridge recused himself upon discerning a potential conflict of interest. Doc. #167. The case was transferred to this Court on January 5, 2022. Doc. #168.

## **II. Legal Standards**

### **a. Federal Rule of Civil Procedure 42(b)**

The trial court has broad discretion in deciding to bifurcate issues, and its ruling will not be reversed on appeal absent a clear abuse of discretion. *Briggs v. State Farm Fire & Cas. Co.*, 673 F. App'x 389, 390 (5th Cir. 2016). However, “[t]here is an important limitation on ordering a separate trial of issues under Rule 42(b): the issue to be tried must be so distinct and separate from the others that a trial of it alone may be had without injustice. This limitation on the use of bifurcation is a recognition of the fact that inherent in the Seventh Amendment guarantee of a trial by jury is the general right of a litigant to have only one jury pass on a common issue of fact.” *McDaniel v. Anheuser-Busch, Inc.*, 987 F.2d 298, 305 (5th Cir. 1993) (emphasis original, internal quotations and citations omitted).

### **b. Federal Rule of Evidence 702**

“The admission or exclusion of expert testimony is a matter left to the discretion of the trial court.” *Primrose Operating Co. v. Nat’l Am. Ins. Co.*, 382 F.3d 546, 563 (5th Cir. 2004). In addition to demonstrating the expert’s specialized knowledge will assist the trier of fact, the proponent of the expert’s testimony must show “(1) the testimony is based upon sufficient facts or data, (2) the testimony is the product of reliable principles and methods, and (3) the witness has

applied the principles and methods reliably to the facts of the case.” FED. R. EVID. 702. “An expert may base an opinion on facts or data in the case that the expert has been made aware of or personally observed.” FED. R. EVID. 703. An expert witness is required to produce an expert report that contains “a complete statement of all opinions the witness will express and the basis and reasons for them,” as well as “the facts or data considered by the witness in forming” said opinions. FED. R. CIV. P. 26(a)(2)(B)(i), (ii). “If a party fails to provide [this] information . . . , the party is not allowed to use that information or witness to supply evidence . . . unless the failure was substantially justified or is harmless.” FED. R. CIV. P. 37(c)(1). Absent such a failure, “in determining the admissibility of expert testimony, the district court should approach its task with proper deference to the jury’s role as the arbiter of disputes between conflicting opinions.” *United States v. 14.38 Acres of Land*, 80 F.3d 1074, 1077 (5th Cir. 1996) (cleaned up).

“Vigorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof are the traditional and appropriate means of attacking shaky but admissible evidence.” *Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579, 596 (1993). “As a general rule, questions relating to the bases and sources of an expert’s opinion affect the weight to be assigned that opinion rather than its admissibility and should be left for the jury’s consideration.” *14.38 Acres of Land*, 80 F.3d at 1077 (cleaned up). Typically, juries should “hear the expert’s testimony and decide whether the predicate facts are accurate.” *Uretekologia De Mexico S.A. De C.V. v. Uretek (USA), Inc.*, 434 F. Supp. 3d 517, 529 (S.D. Tex. 2020). Courts are narrowly tasked with making “a preliminary assessment of whether the reasoning or methodology underlying the testimony is scientifically valid and of whether that reasoning or methodology properly can be applied to the facts in issue.” *Daubert*, 509 U.S. at 592–93. The focus “must be solely on principles and methodology, not on the conclusions they generate.” *Id.* at 595.

### **III. Analysis**

#### **a. Defendant's Motion to Bifurcate**

Defendants argue that Plaintiff's claims against Ethicon are barred under Texas law because she filed this lawsuit outside of the two-year statute of limitations period. Doc. #155 at 6. Under Texas law, when the discovery rule applies, "the claims accrue not when the wrongful conduct first causes a legal injury, but when the claimant first 'knew or . . . should have known of the wrongful act and resulting injury.'" *Regency Field Services, LLC v. Swift Energy Operating, LLC*, 622 S.W.3d 807, 817 (Tex. 2021) (quoting *S.V. v. R.V.*, 933 S.W.2d 1, 4 (Tex. 1996)). Because the limited question of whether Plaintiff's claims are time-barred is separate from the question of liability, causation and damages, Defendants moves to bifurcate the trial to try the statute-of-limitations issue first. Doc. #155 at 7. Defendants admit that the Court has broad discretion in determining this issue. *Id.*

Defendants first argue that bifurcation is efficient and will save the Court and parties significant time and resources. *Id.* at 8–12. However, Defendants did not take advantage of their opportunity for even greater efficiency—filing a dispositive motion by the deadline. Doc. #76. Moreover, Defendants' Motion for Leave to file after the deadline was denied for lack of sufficient explanation. Doc. #159 at 3. Next, Defendant argues that bifurcation is necessary to avoid prejudice and confusion. Doc. #155 at 12–14. The Court is not persuaded. The concept of an affirmative defense is that the defendant argues that the plaintiff's claims are not true, but if they are true, then the claims fail for an alternative reason. The parties' arguments and the jury charge can effectively compartmentalize the issues for the jury, including addressing the limitations issue. Furthermore, the potential prejudice faced by Defendants is outweighed by potential prejudice faced by Plaintiff if forced to present her evidence at two trials. Therefore, Defendants' Motion to Bifurcate is denied.

**b. Defendant's Motion to Limit Dr. Michaels**

Defendants contend that Dr. Michaels' specific causation opinions are unreliable and should be excluded as inadmissible. Defendants first argue that Dr. Michaels impermissibly formed his diagnosis without any pathological evidence related to Barone's mesh devices. Doc. #140 at 8. However, Dr. Michaels reviewed pathology slides cut from material explanted by Dr. Lotze during Plaintiff's August 13, 2014 procedure. Doc. 140, Ex. 1 at 4. Dr. Michaels' opinions are consistent with the conclusion of the treating physician. Doc. #150, Ex. 12 at 2. Dr. Michaels also examined tissue from Plaintiff's September 11, 2018 operation. Doc. #140, Ex. 1 at 29. Only after reviewing this material did he make conclusions related to that operation. *Id.* at 30, 31. As such, the Court finds Defendants' argument that Dr. Michaels reviewed no pathological evidence to be contrary to the record.

Defendants next argue that Dr. Michaels' report is questionable because he (1) did not compare Plaintiff's mesh slides to a control, (2) did not provide a basis for his leap from correlation to causation, and (3) failed to consider alternative causes of her condition. Doc. #140 at 9–16. To be clear, Defendants do not argue that Dr. Michaels is unqualified, but instead that there are analytical gaps between his observations and his conclusions. *Id.* The Court finds that Defendants' attempt to undermine the weight of Dr. Michaels' opinions is more properly suited for cross examination and presentation of contrary evidence than the exclusion of testimony from an undisputedly qualified expert. *See Daubert*, 509, U.S. at 596 and *14.38 Acres of Land*, 80 F.3d at 1077.

Lastly, Defendant argues that Dr. Michaels' opinions regarding mesh erosion and infections are unsupported and inadmissible because he does not discuss these symptoms in the body of his initial report. Doc. #140 at 16, 17. However, an expert may "base an opinion on facts or data in the case that the expert has been made aware of or personally observed." FED. R. EVID.

703. Dr. Michaels' opinions regarding erosion and infection are supported by the clinicians documenting it, cited literature, and pathology findings consistent with the erosion of mesh. Doc. #150 Ex. 1 at 3–5, 27; Ex. F. at 2–3; and Ex. R. Once again, Defendants' attempt to undermine the weight of Dr. Michaels' opinions is more properly suited for cross examination and presentation of contrary evidence. *See Daubert*, 509, U.S. at 596 and *14.38 Acres of Land*, 80 F.3d at 1077. Accordingly, Defendants' Motion to Limit Dr. Michaels is denied.

**c. Defendant's Motion to Limit Dr. Elliott**

Defendants contend that Dr. Elliot's specific causation opinions are unreliable and should be excluded as inadmissible. Defendants argue that a significant portion of his report is a narrative history of the development of pelvic mesh devices, and not a proper subject of expert testimony. Doc. #141 at 4, 5. However, that portion of Dr. Elliot's report describes facts and references regarding pelvic anatomy, the characteristics of the devices at issue, benefits and risks associated with those devices, and medical authority upon which Dr. Elliot relies to offer certain opinions. Doc. # 149, Ex. 1 at 5–58. Defendants also make relevance arguments regarding Dr. Elliott's opinions on several issues. Doc. #141 at 7–16. Relevance is well-covered by the Federal Rules of Evidence. FED. R. EVID. 401–403. The Court will listen to Dr. Elliot's testimony at trial, and if the Court concludes that he, or any expert, is opining on matters not relevant to the issues at hand or that the expert's testimony is not admissible for other reasons, the Court will sustain an appropriate objection in accordance with the Federal Rules of Evidence.

Defendants next argue that Dr. Elliot's specific causation opinions are unreliable because he did not perform a reliable differential diagnosis. Doc. #141 at 5, 6. Like their argument regarding the reliability of Dr. Michaels' report, Defendants do not argue that Dr. Elliot is unqualified. *Id.* Instead, they argue that there are analytical gaps between his observations and his conclusions. *Id.* Once again, the Court finds that Defendants' attempt to undermine the weight



of Dr. Elliot's opinions is more properly suited for cross examination and presentation of contrary evidence than the exclusion of testimony from an undisputedly qualified expert. *See Daubert*, 509, U.S. at 596 and *14.38 Acres of Land*, 80 F.3d at 1077.

Lastly, Defendant argues that Dr. Elliott's case-specific opinions that are the same as his previous excluded general opinions should be excluded. Doc. #141 at 16–17. The MDL Court previously limited Dr. Elliott's general opinion testimony in certain ways. *In re Ethicon Inc. Pelvic Repair Sys. Prod Liab. Litig.*, 2016 WL 4500766 at \*3–6. (S.D. W.Va. 2016). Dr. Elliot has been designated as both a general and case-specific expert in this case. Doc. #149, Ex. 6. Regarding his case-specific opinions, the Court will listen to his testimony at trial and sustain or overrule objections to admissibility as appropriate. *See Daubert*, 509, U.S. at 596 and *14.38 Acres of Land*, 80 F.3d at 1077.

#### **IV. Conclusion**

The Court determines that bifurcating is not in the best interest of efficiency and minimizing potential prejudice. Therefore, Defendants' Motion to Bifurcate is DENIED. Further, the Court finds that Defendants' evidentiary objections are better suited for cross examination, presentation of contrary evidence, and objections in accordance with the Federal Rules of Evidence as opposed to prematurely excluding testimony of qualified experts. Accordingly, both Defendants' Motions to Limit Dr. Michaels and to Limit Dr. Elliot are hereby DENIED.

It is so ORDERED.

**MAR 29 2022**

Date



The Honorable Alfred H. Bennett  
United States District Judge